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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/269,845	09/24/1999	MARIN JANUSZ	AAT-11612	1703

7590 04/20/2004

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EXAMINER

TELLER, ROY R

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 04/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/269,845	Applicant(s) JANUSZ ET AL.	
	Examiner Roy Teller	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15, 16, 24, 26-32, 35, 40, 41, 54 and 58-68 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 24, 26-30 and 58-63 is/are allowed.
- 6) ☒ Claim(s) 15, 16, 31, 32, 35, 40, 41, 54, and 64-68 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is in response to the RCE, filed 1/27/04. Applicant has amended claims 15 and 16. Claims 15, 16, 24, 26-32, 35, 40, 41, 54, and 58-68 are pending.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 15, 16, 31, 32, 64 and 65 are rejected under 35 U.S.C. 102(b) as being anticipated by Janusz (Archivum Immunologiae et Therapiae Experimentalis, 1993, vol.41, pp-275-279), by Zimecki (Archivum Immunologiae et Therapiae Experimentalis, 1991, vol. 39, pp-461-467), or by Hraba (Archivum Immunologiae et Therapiae Experimentalis, 1986, vol. 34, pp- 437-443).

A composition (e.g., medicament, pharmaceutical composition, dietary supplement) comprising colostrinin or a nonapeptide therein is claimed.

Each of the cited references teach therapeutic bioactive compositions comprising proline-rich polypeptide (PRP) isolated from colostrum- which as readily admitted by Applicants, is now well known as colostrinin (see, e.g., page 1, lines 18-19, of the instant specification). Further, Janusz et al. expressly teach the instantly claimed nonapeptide having bioactivity. In addition (as

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evidenced by Janusz et al.), please note that the PRP preparations taught by the other cited references would inherently comprise the claimed nonapeptide. See entire documents.

Non-ovine Colostrinin is the same product as ovine Colostrinin (as stated by Dr. Kruzel in an in-person interview, USPTO, 4/13/04).

Accordingly, each of the cited references is deemed to anticipate the above claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 15, 16, 31, 35, 40, 41, 54, and 64-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Janusz (Archivum Immunologiae et Therapiae Experimentalis, 1993, vol.41, pp-275-279), Zimecki (Archivum Immunologiae et Therapiae Experimentalis, 1991, vol. 39, pp-461-467), or Hraba (Archivum Immunologiae et Therapiae Experimentalis, 1986, vol. 34, pp-437-443).

The references are relied upon for the reasons set forth above. The adjustment of particular conventional working conditions (e.g., providing such colostrinin-containing

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composition within conventional and convenient human dosage forms such as within tablets, lozenges, gels, etc.), is deemed clearly to be a mere matter of judicious selection and routine optimization which is well within the purview of the skilled artisan, based upon the overall beneficial teachings provided by one or more of the cited references with respect to the therapeutic bioactivity of such colostrinin (PRP) compositions.

With respect to the cited art rejections above, it is noted that the cited references do not teach that their compositions can be used in the manner instantly claimed, however, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting. Please note that when applicant claims a composition in terms of functions and the composition of the prior art appears to be the same, the Examiner may make a rejection under 35 U.S.C. 102 and 103 (MPEP 2112).

Conclusion

Claims 24, 26-30 and 58-63 are allowed. Claims 15, 16, 31, 32, 35, 40, 41, 54, and 64-68 are rejected.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy Teller whose telephone number is (571) 272-0971. The examiner can normally be reached on Monday-Friday from 5:30 am to 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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CHRISTOPHER R. TATE
PRIMARY EXAMINER